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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,313

Applicant(s)

KARINKA ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) see Other.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS of May 21, 2002 and of November 13, 2003.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrode-bearing support of a second electrode support must be shown or the features canceled from the claim 14. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 14 is objected to because of the following informalities: there are two sections labeled "(b)" and two sections labeled "(c)".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 14-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 14 recites the limitation "said electrode-bearing major surface of said first electrode support" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim; and

b) Claim 14 recites the limitation "said electrode-bearing major surface of said second electrode support" in lines 14-15. There is insufficient antecedent basis for this limitation in the claim.

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Maley et al. (US 5,494,462), hereafter "Maley".

Addressing claim 1, Maley teaches a biosensor strip (abstract) comprising

(a) an electrode support (62);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (90), the working electrode comprising a working ink (96) deposited on an electrically conductive material (66);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (86); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (88 and col. 13, ll. 15-20).

Note that barring a contrary showing, screen-printed electrode paste or solution is synonymous with electrode ink.

Addressing claim 2, in Maley the reference electrode comprises a silver/silver chloride "ink" (col. 6, ll. 1-5 and col. 16, ll. 14-26).

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Addressing claim 3, the reference electrode comprises silver (col. 13, ll. 1-5).

Addressing claim 10, a covering layer (72) as claimed is disclosed in Maley (Figures 9A, 10, and 11).

Addressing claim 11, a mesh (94) as claimed is disclosed in Forrow (Figures 9A, 10, and 11).

Addressing claim 13, Maley teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

- (a) providing the biosensor strip of claim 1 (see the rejection of claim 1, above);
- (b) applying the biological fluid to the biosensor strip (implied by Figures 12-24, which show test results for various samples and biosensor conditions);
- (c) inserting the biosensor strip into an analyte monitor (Figure 2);
- (d) applying a voltage at the working electrode with respect to the reference electrode (implied by Figures 12 and 13, for example, which show current responses for different concentration of glucose and lactate, respectively);
- (e) measuring the current flowing between the working electrode and the counter electrode (implied by Figures 12 and 13, for example, which show current responses for different concentration of glucose and lactate, respectively); and
- (f) correlating the current measured to the concentration of the analyte (Figures 12 and 13).

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6. Claims 1-3, 5, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (US 5,571,395), hereafter "Park".

Addressing claim 1, Park teaches a biosensor strip (abstract) comprising

(a) an electrode support (1);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (3), the working electrode comprising a working ink (col. 6, ll. 56-58) deposited on an electrically conductive material (2-1);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (5); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (4 and col. 6, ll. 56-58).

Note that barring a contrary showing, screen-printed electrode paste or solution is synonymous with electrode ink.

Addressing claim 2, in Park the reference electrode comprises a AgCl "ink" (col. 6, ll. 56-63).

Addressing claim 3, the reference electrode comprises silver (col. 6, ll. 56-62).

Addressing claim 5, a working ink comprising an enzyme and a mediator is disclosed (col. 6, ll. 34-47 and col. 8, ll. 41-50).

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Addressing claim 10, a covering layer (6) as claimed is disclosed in Park (Figures 1 and 3).

Addressing claim 11, a mesh (8) as claimed is disclosed in Forrow (Figure 1 and col. 7, ll. 5-7).

Addressing claim 13, Park teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

- (a) providing the biosensor strip of claim 1 (see the rejection of claim 1, above);
- (b) applying the biological fluid to the biosensor strip (implied by Figure 6, which shows test results for various ethyl alcohol concentrations);
- (c) inserting the biosensor strip into an analyte monitor (Figure 10);
- (d) applying a voltage at the working electrode with respect to the reference electrode (implied by Figure 6, which show current responses for different concentration of ethyl alcohol);
- (e) measuring the current flowing between the working electrode and the counter electrode (implied by Figure 6, which show current responses for different concentration of ethyl alcohol); and
- (f) correlating the current measured to the concentration of the analyte (Figure 6).

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7. Claims 1-3, 5, 10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yee et al. (US 5,672,256), hereafter "Yee".

Addressing claim 1, Yee teaches a biosensor strip (abstract) comprising

(a) an electrode support (1);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (6a1, 6a2, or 6a3), the working electrode comprising a working ink deposited on an electrically conductive material (col. 4, ll. 63-67);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (5); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (7 and col. 4, ll. 63-67).

Note that barring a contrary showing, screen-printed electrode paste or solution is synonymous with electrode ink.

Addressing claim 2, in Yee the reference electrode comprises a carbon "ink" (col. 4, ll. 63-67).

Addressing claim 3, the reference electrode comprises silver (col. 4, ll. 59-62).

Addressing claim 5, a working ink comprising an enzyme and a mediator is disclosed (col. 5, ll. 13-20).

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Addressing claim 10, a covering layer (4) as claimed is disclosed in Yee (Figures 3 and 4).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode (as seen from Figure 3 the working electrode is below the reference electrode and the reference electrode is below the counter electrode. So if sample is introduced at the bottom of the measurement zone defined by layer 4 when the sample flows to cover the measurement zone it will first contact the working electrode, then the reference electrode and then the counter electrode.).

Addressing claim 13, Yee teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

- (a) providing the biosensor strip of claim 1 (see the rejection of claim 1, above);
- (b) applying the biological fluid to the biosensor strip (implied by Figure 7, which shows test results for various ethyl alcohol concentrations);
- (c) inserting the biosensor strip into an analyte monitor (implied by Figure 7, which shows test results for various ethyl alcohol concentrations, together with Figure 3, which shows a connection pad at the bottom of the strip);
- (d) applying a voltage at the working electrode with respect to the reference electrode (stated in col. 4, ll. 53-56 and implied by Figure 7, which shows test results for various ethyl alcohol concentrations);

- (e) measuring the current flowing between the working electrode and the counter electrode (implied by Figure 7, which shows test results for various ethyl alcohol concentrations); and
- (f) correlating the current measured to the concentration of the analyte (Figure 7).

8. Claims 1, 3-7, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al. (US 6,309,526 B1), hereafter "Fujiwara".

Addressing claim 1, Fujiwara teaches a biosensor strip (abstract) comprising

- (a) an electrode support (1);
- (b) a first electrode disposed on the electrode support, the first electrode being a working electrode (4), the working electrode comprising a working ink deposited on an electrically conductive material (col. 3, ll. 1-2 and col. 3, ll. 14-18);
- (c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (5); and
- (d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (5 and col. 3, ll. 1-3).

Note that barring a contrary showing, (a) the reagent layer is synonymous with the working electrode ink, and (b) a reference electrode can structurally and compositionally be the same as a counter electrode. As described in Applicant's specification, the

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reference electrode differs from the counter electrode in that current passes through the counter electrodes while the reference electrode is held at a fixed potential and has minimal current passing through it; these are solely intended uses.

Addressing claim 3, the reference electrode comprises metal (col. 2, ll. 50-55).

Addressing claim 4, the ink on the working electrode is also on the reference electrode (col. 3, ll. 14-15).

Addressing claim 5, a working ink comprising an enzyme and a mediator is disclosed (col. 1, ll. 22-25).

Addressing claim 6, glucose oxidase is disclosed (col. 1, ll. 22-24).

Addressing claim 7, ferricyanide is disclosed (col. 3, ll. 14-20).

Addressing claim 10, a covering layer (8) as claimed is disclosed in Fujiwara (Figures 1d and 2).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode (as seen from Figures 1d and 2, the

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sample flow path requires the sample to flow over the electrodes in sequence. If sample is introduced at the flow path end proximate the viewer and proximate electrode 5 is taken to be the “reference” electrode and distal electrode 5 is taken to be the “counter” electrode, then the electrodes are positioned as claimed, since electrode 4 is the working electrode).

9. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Winarta et al. (US 6,287,451 B1), hereafter “Winarta”.

Addressing claim 1, Winarta teaches a biosensor strip (abstract) comprising

(a) an electrode support (**20**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**W2**), the working electrode comprising a working ink deposited on an electrically conductive material (col. 9, ln. 66 – col. 10, ln. 6 and col. 10, ll. 49-60);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**R**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (**W2** and col. 9, ln. 66 – col. 10, ln. 6).

Note that barring a contrary showing, (a) the reagent solution for **W2** is synonymous with the working electrode ink, and (b) a reference electrode can structurally and compositionally be the same as a counter electrode. As described in Applicant’s

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specification, the reference electrode differs from the counter electrode in that current passes through the counter electrodes while the reference electrode is held at a fixed potential and has minimal current passing through it; these are solely intended uses.

Addressing claim 2, **W2** comprises the same ink as the reference electrode **R** (col. 10, ll. 41-48).

Addressing claim 3, the reference electrode comprises metal (col. 9, ln. 66 – col. 10, ln. 3).

Addressing claim 4, the reference electrode comprises an ink similar to that used in the working electrode **W2** (col. 8, ll. 43-52).

Addressing claim 5, a working ink comprising an enzyme and a mediator is disclosed (col. 10, ll. 49-58).

Addressing claim 6, glucose oxidase is disclosed (col. 10, ll. 49-58).

Addressing claim 7, ferricyanide is disclosed (col. 10, ll. 49-58).

Addressing claim 8, ferrocene is disclosed (col. 8, ll. 36-40).

Addressing claim 10, a covering layer (40) as claimed is disclosed in Winarta (Figure 2).

10. Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrow et al. (WO 99/19507), hereafter "Forrow".

Addressing claim 1, Forrow teaches a biosensor strip (abstract) comprising

- (a) an electrode support (1);
- (b) a first electrode disposed on the electrode support, the first electrode being a working electrode (5), the working electrode comprising a working ink (16) deposited on an electrically conductive material (4);
- (c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (6); and
- (d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (7).

Also see page 11, ll. 5-22.

Note that barring a contrary showing, although Forrow refers to the third electrode (7) as an "indicator" electrode and not as a "counter" electrode these labels are only intended uses that do not necessarily imply a difference in structure or composition. Forrow, for example, teaches that the reference electrode may be identical to the working electrode (page 16, lines 17-19). As discussed in Applicant's specification (page 2), the purpose of the counter electrode is to balance the oxidation or reduction reaction that occurs at the working electrode.

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Addressing claims 2 and 4, Forrow discloses that the reference electrode may comprise reference ink, which is the same as the working ink (page 16, lines 17-26).

Addressing claim 3, several suitable conductive materials for the reference electrode are disclosed (page 22, lines 1-3).

Addressing claim 5, providing enzyme and mediator in the working ink is disclosed (for example, *Table 2* on page 18).

Addressing claim 6, glucose dehydrogenase is disclosed (*Table 2* on page 18).

Addressing claim 9, phenanthroline quinone and derivatives thereof are disclosed (*Table 2* on page 18 and page 7, lines 1-9).

Addressing claim 10, a covering layer (**15, 18, 20, or 21**) as claimed is disclosed in Forrow (Figure 1).

Addressing claim 11, a mesh (**17 or 19**) as claimed is disclosed in Forrow (Figure 1).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode

11. Claims 14-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Feldman et al. (US 6,592,745 B1), hereafter "Feldman".

Addressing claim 14, Feldman teaches a biosensor strip (abstract) comprising

- (a) a first electrode support with an electrode-bearing surface (**508** in Figure 18C or **38** in Figure 1);
- (b) a cover layer (**500** or second support **38**);
- (c) a spacer layer interposed between the electrode support and the cover layer (**504** or **28**);
- (d) a first electrode, the first electrode being a working electrode, the working electrode comprising working ink deposited on an electrically conductive material (**502** and col. 31, ll. 65-67 or **22**);
- (e) a second electrode, the second electrode being a reference electrode (**510** and col. 32, ll. 15-24 or col. 24, ll. 44-45);
- (f) a third electrode, the third electrode being a counter electrode, the counter electrode being comprising an electrically conductive material (**512** col. 32, ll. 21-24 or **24**); and

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(g) a second electrode support with an electrode-bearing surface facing the electrode-bearing surface of the first electrode support (Figures 18A-C or second support 38. Note claim 25 seems to imply that the one of the electrode supports can also be the cover).

Addressing claims 15 and 16, Ag/AgCl ink is disclosed (col. 32, ll. 15-19 and col. 24, ll. 41-48). Furthermore, for claim 16 if the reference electrode did not comprise a conductive material it could not function as a reference electrode.

Addressing claim 17, Ag/AgCl or Ag/AgBr may be deposited on silver chloride or silver base (col. 24, ll. 45-48). Note that "working" ink is not necessarily different from "reference" ink. These labels only suggest intended uses. Indeed, Feldman discloses that the same materials and methods may be used to make the counter electrode (reference electrode) and the working electrode (col. 24, ll. 48-52).

Addressing claim 18, an enzyme and a mediator in the working ink is disclosed (col. 8, ll. 35-51 and col. 24, ll. 14-36).

Addressing claim 19, both glucose oxidase and glucose dehydrogenase are disclosed (col. 24, ll. 22-25).

Addressing claim 20, ferricyanide is disclosed (col. 22, ll. 13-24).

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Addressing claim 21, ferrocene is disclosed (col. 15, ll. 33-34).

Addressing claim 22, various phenoquinones are disclosed (col. 20, ln. 66 – col. 21, ln. 13).

Addressing claim 23, an adhesive in the spacer layer is disclosed (col. 27, ll. 31-32 and col. 32, ll. 44-55).

Addressing claim 24, a pressure-sensitive adhesive is disclosed (col. 26, ll. 40-46).

Addressing claim 25, having an electrode disposed on the electrode support and another electrode disposed on the cover is disclosed (Figures 1 and 18A-C).

Addressing claim 26, as seen from Figures 18A-C the sample enters the biosensor entrance entrance (514) and contacts the working electrode (502) and the reference electrode (510) before contacting the counter electrode (512).

Addressing claim 27, Feldman teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

- (a) providing the biosensor strip of claim 14 (see the rejection of claim 14, above);
- (b) applying biological sample to the biosensor strip (col. 53, ll. 40-47);

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- (c) inserting the biosensor strip into an analyte monitor (implied by col. 24, ll. 52-55 and col. 31, ll. 17-19, which teach tabs or contact regions for connection to a measuring device);
- (d) applying a voltage at the working electrode with respect to the reference electrode (col. 53, ll. 33-37);
- (e) measuring the current flowing between the working electrode and the counter electrode (col. 53, ll. 53-55); and
- (f) correlating the current measured to the concentration of the analyte (Table 1 in column 54 and col. 54, ll. 29-38).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1042.

Alex Noguera

Alex Noguera

01/06/04

Primary Examiner
TC 1753